



# UNIVERSITY OF NICOSIA

## ΠΑΝΕΠΙΣΤΗΜΙΟ ΛΕΥΚΩΣΙΑΣ

<b>Course Code</b> PHAR 455	<b>Course Title</b> Pharmacovigilance and Pharmacoepidemiology / Φαρμακοεπαγρύπνηση και Φαρμακοεπιδημιολογία	<b>Credits (ECTS)</b> 4
<b>Department</b> Life & Health Sciences	<b>Semester</b> Fall	<b>Prerequisites</b>
<b>Type of Course</b> Required	<b>Field</b> Pharmacy	<b>Language of Instruction</b> Greek/English
<b>Level of Course</b> 1 <sup>st</sup> Cycle	<b>Year of Study</b> year	<b>Lecturer</b> Christos Petrou/Nicolas Stylianides/Staff
<b>Mode of Delivery</b> face-to-face	<b>Work Placement</b> N/A	<b>Co-requisites</b> None

### Objectives of the Course:

The pharmacoepidemiology course is an introduction to the evaluation of the scientific studies that supports the rational use of medication use in humans. This course provides opportunities for students to understand the concepts, methods, and applications of epidemiology and outcomes studies utilized in clinical settings as well as to provide tools to critically assess the clinical literature. In addition, the methods for the interpretational and generalization of findings from studies relevant to medical and pharmaceutical care practice will be discussed.

Drug safety monitoring and risk management are vitally important for medicinal product developers, licence holders and clinical investigators. In addition to their duty to protect public health, increasingly tight regulation and potentially massive payments to litigants provide strong incentives for pharmaceutical and biotechnology companies to ensure that they maintain efficient systems for drug safety / pharmacovigilance and that all staff are aware of the basic requirements. This course will provide them with an overview of the most important aspects of this discipline, both before and after marketing of products, especially as they apply in Europe.

### Learning Outcomes:

After completion of the course students are expected to:

- 1.) At completion of the course the student will be able to recognize drug safety issues and develop appropriate strategies to optimize the benefit/risk ratio of the product involved and to report adverse drug reactions of high quality
- 2.) Is expected to be able to read and understand a study protocol in a clear, and simple, manner
- 3) will be able to understand the main principles of Pharmacoepidemiology

**Course Contents:****Pharmacoepidemiology**

1. Various methods to collect pharmacoepidemiological information is a central topic.
2. Drug utilization studies, cross-section studies, observational studies and clinical trials.
3. Spontaneous reporting of side-effects.
4. The design of studies.
5. Data collection about drug exposure and outcome, bias and the significance of confounders.
6. The causality and the significance of pharmacoepidemiological studies for drug assessment.

**Pharmacovigilance**

This course will deliver an introduction to the basics of drug safety and pharmacovigilance, including regulatory requirements, adverse event reporting, signaling and risk management. This course addresses the regulatory issues across global government agencies that improve safety, but slow down the product approval process. Keeping products on the market without interruption becomes more essential with the reduced pipeline of drugs in development. Successful navigation of drug safety and pharmacovigilance are keys to product longevity, consumer confidence, and regulatory compliance. This course will provide learners with the regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet international standards .

Thalidomide and History of Pharmacovigilance; Limitations of Pre-approval Clinical Trials; Post-Marketed AEs; Pharmacovigilance Definitions; Assessing Adverse Events; Serious vs. Severe; Causality; Expectedness; SUSAR; Minimum Criteria for Reporting; Reporting Format; Managing Blinded Therapy Cases; Sponsor's Responsibilities; Sponsor's Responsibilities; Monitor Responsibilities; Principal Investigator Responsibilities; Adverse Reaction Types; Safety Signal Generation. Safety and reporting standards.

Matrix of Safety Regulations; International Conference on Harmonisation (ICH); CIOMS; Key EU Components

**Learning Activities and Teaching Methods:**

Lectures, class discussion, assignments, practicals

**Assessment Methods:**

Final Examination 60%, course work 40%

**Required Textbooks/Reading:**

Authors	Title	Publisher	Year	ISBN
Hartzema AG, Tilson HH and Chen A.	Pharmacoepidemiology and Therapeutic Risk Management .	Harvey Whitney Press, Inc.	Cincinnati	2008
Hartzema AG, Porta M, Tilson HH.	Pharmacoepidemiology: An Introduction.			
	An Introduction to Pharmacovigilance .	Wiley-Blackwell,		2009.

Wang D, Bahkai A.
Friedman LM, Furberg CD, DeMets DL. Fundamentals of Clinical Trials

**Recommended Textbooks/Reading:**

Authors	Title	Publisher	Year	ISBN